

2. **The Examiner has Failed to Establish a *Prima Facie* Case of Obviousness**

Claims 1-3, 7 and 9 are rejected under 35 U.S.C. §103(a), as allegedly obvious over Langer and Udall. A *prima facie* case of obviousness requires the Examiner to cite a combination of references which (a) disclose the elements of the claimed invention, (b) suggests or motivates one of skill in the art to combine those elements to yield the claimed combination, and (c) provides a reasonable expectation of success should the claimed combination be carried out. Failure to establish any one of these three requirements precludes a finding of a *prima facie* case of obviousness, and, without more, entitles Applicant to allowance of the claims in issue.³ In addressing this rejection, Applicants focus on the independent claims since non-obviousness of an independent claim necessarily leads to non-obviousness of claims dependent therefrom.⁴

Before responding to the obviousness rejection, Applicants wish to make of record the fact the Examiner, in issuing the Final Office Action, completely ignored and failed to respond to Applicants detailed traversal of the rejection in the previous Amendment and Response. The Examiner's sum total response to the Applicants arguments is that "Applicant's argue that there is no motivation to combine. However, motivation is provided." This conclusory statement fails to be responsive to Applicants traversal. Furthermore, the Examiner failed completely to respond to Applicants arguments regarding failure to teach all elements of the claims and reasonable expectation of success.

Instead of responding to Applicants traversal, the Examiner essentially repeated verbatim the rejections from the previous Office Action. This approach is not looked upon with favor by the Federal Circuit and does not conform with proper patent practice according to the Manual of Patent Examining Procedure (MPEP). The Examiner must respond to all of the arguments and evidence presented by Applicants. The MPEP states that:

Office personnel should consider all rebuttal arguments and evidence presented by applicants. . . . *In re Beattie*, 974 F.2d 1309, 1313, 24 USPQ2d 1040, 1042-43 (Fed. Cir. 1992). . . . **Office personnel should avoid giving evidence no weight**, except in rare circumstances. *Id. See also In re Alton*, 76 F.3d 1168, 1174-75, 37 USPQ2d 1578, 1582-83 (Fed. Cir. 1996).

³ See, e.g., *Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990).

⁴ §MPEP 2143.03.

* * *

A determination under 35 U.S.C. 103 should rest on **all the evidence** and should not be influenced by any earlier conclusion. *See, e.g., Piasecki*, 745 F.2d at 1472-73, 223 USPQ at 788; *In re Eli Lilly & Co.*, 902 F.2d 943, 945, 14 USPQ2d 1741, 1743 (Fed. Cir. 1990). Thus, once the applicant has presented rebuttal evidence, Office personnel should **reconsider** any initial obviousness determination in view of the entire record. *See, e.g., Piasecki*, 745 F.2d at 1472, 223 USPQ at 788; *Eli Lilly*, 902 F.2d at 945, 14 USPQ2d at 1743.⁵

Additionally, the Courts have held as follows:

When *prima facie* obviousness is established and evidence is submitted in rebuttal, the decision-maker must start over An earlier decision should not . . . be considered as set in concrete, and applicant's rebuttal evidence then be evaluated only its knockdown ability. Analytical fixation on an earlier decision can tend to provide the decision with an undeservedly broadened umbrella effect. *Prima facie* obviousness is a legal conclusion, not a fact. Facts established by rebuttal evidence must be evaluated along with the facts on which the earlier conclusion was reached, not against the conclusion itself. Though the tribunal must begin anew, a final finding of obviousness may of course be reached, but such finding will rest upon evaluation of all facts in evidence, uninfluenced by any earlier conclusion reached . . . upon a different record.⁶

Furthermore:

If a *prima facie* case is made in the first instance, and if the applicant comes forward with a reasonable rebuttal, whether buttressed by experiment, prior art references, or argument, the entire merits of the matter are to be reweighed.⁷

Accordingly, even if the Examiner had established a *prima facie* of obviousness in the preceding Office Action (and Applicants contend that she did not), the Examiner must respond to Applicants arguments.

It is particularly problematic that the Examiner, while finalizing the present office action, failed to address all of the Applicants arguments, thereby necessitating repeating those arguments in this Response. Accordingly, Applicants request that the obviousness rejections of the claims be removed.

⁵ MPEP §§2144.08; emphasis added).

⁶ *In re Rinehart*, 531 F.2d 1048, 1052, 189 USPQ 143, 147 (CCPA 1976).

⁷ *In re Hedges*, 783 F.2d 1038, 1039, 228 USPQ 685, 686 (Fed. Cir. 1986).

a. No Motivation to Combine the References

When applying 35 U.S.C. §103, the references must be considered as whole and must suggest the desirability and thus the obviousness of making the combination.⁸ Applicants further submit that references cannot be considered collectively until the Examiner points to some motivation to combine those references. The purpose behind this requirement is to prevent the Examiner from using the invention itself and hindsight reconstruction to defeat the patentability of the invention. The Federal Circuit, in a recent decision, articulates this position:

To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the examiner to show a motivation to combine the references that create the case of obviousness. In other words, the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.⁹

The references do not suggest the desirability of making the combination. The Examiner states:

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use CLA in the method of reducing blood pressure by losing weight of Langer to achieve the beneficial effect of weight loss by taking CLA in view of Udell.¹⁰

Applicants respectfully submit that by making these statements, the Examiner has not shown reasons why a skilled artisan would make the combination; she has only stated what she believes each reference teaches in isolation from the other reference and then stated that it would be obvious to combine the elements. In order to support the combination, the Examiner has made a **conclusory** statement based on the level of skill in the art. This is not

⁸ *Hodash v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143, n. 5, 229 USPQ 182, 187, n.5 (Fed. Cir. 1986).

⁹ *See In re Rouffet et al.*, 149 F.3d 1350, 47 USPQ2d 1453 (Fed. Cir. 1998).

¹⁰ Office action, page 3.

permissible. Such unsupported statements are exactly what the *Rouffet* court sought to prevent. The Federal Circuit stated:

The Board did not . . . explain what specific understanding or technological principal within the knowledge of one of ordinary skill in the art would have suggested the combination. **Instead, the Board merely invoked the high level of skill in the art.** If such a rote invocation could suffice to supply a motivation to combine, the more sophisticated scientific fields would rarely, if ever, experience a patentable technological advance. Instead, in complex scientific fields, the Board could routinely identify the prior art elements in an application, invoke the lofty level of skill, and rest its case for rejection. To counter this potential weakness in the obviousness construct, the suggestion to combine requirement stands as a critical safeguard against hindsight analysis and rote application of the legal test for obviousness (Emphasis added).¹¹

Indeed, the Federal Circuit has made it clear that "[b]road, **conclusory** statements regarding the teachings of multiple references, standing alone, are not 'evidence.'"¹² The Examiner has not "shown reasons" or provided "evidence" of why there is a motivation to combine. Instead, the Examiner impermissibly makes a broad, **conclusory** statement, apparently relying on the high level of skill in the art to guide the modification because absolutely no other reasoning is provided. It must be emphasized that the Examiner has provided **no reasons** for why the references should be combined. The Examiner's apparent reliance on the high level of skill in the art is expressly forbidden by the Federal Circuit.

Furthermore, with regard to Claim 9, the Examiner states that "it is well known in the art to determine the appropriate intake dosing by monitoring blood pressure, and body weight individually in order to achieve the treatment of hypertension."¹³ The Examiner provides absolutely no support for this statement. The MPEP requires scientific points made by the Examiner be suggested by reference to a document:

Assertions of technical facts in areas of esoteric technology must always be supported by citation to some reference work.¹⁴

¹¹ *Rouffet*, 47 USPQ2d at 1458.

¹² *In re Dembiczak*, 175 F.3d 994, 50 USPQ2d 1614 (Fed. Cir. 1999)(emphasis added).

¹³ Office Action, page 3.

¹⁴ MPEP 2144.03.

In other words, the Examiner is obliged to put forward **evidence** negating patentability, not baseless suppositions.¹⁵ This rule safeguards the Applicant from the unreasonable burden of having to rebut arguments not based on evidence or sound reasoning. The Examiner has failed to meet this burden. To illustrate the Examiner's lack of support, consider the fact that the two references cited are no better than any two references that randomly mention CLA and hypertension. There is simply nothing in these references or in the art as a whole to suggest the novel use of CLA that is claimed. In fact, the Langer reference directly refutes the Examiner's reasoning by teaching at page 1133 that there is a "relatively weak relation between weight loss and blood pressure" Given this "relatively weak relation" Applicants fail to understand how the Examiner can make the leap from the effects of CLA on body composition to the use of CLA to treat hypertension. Accordingly, Applicants submit that the Examiner has not established a prima facie case of obviousness and request that the obviousness rejected be removed and the claims passed to allowance.

b. References do not Teach All of the Elements of the Claims

Even if the motivation to combine was proper, and Applicants contend that it is not, the references do not teach each element of the Claims. In particular, the references do not teach administering CLA to reduce blood pressure. The references, alone or combined, are completely silent as to this novel use of CLA. As described above in detail, the Examiner has provided no support from either of these references indicating that CLA is useful for treating hypertension. Thus, the references do not provide the claim element of administering CLA to reduce blood pressure. As described above, the Langer reference directly refutes the Examiner's proposed weight reduction/hypertension argument by teaching at page 1133 that there is a "relatively weak relation between weight loss and blood pressure" Given this "relatively weak relation" Applicants fail to understand how a person ordinarily skilled in the art could arrive at the claim element of administering CLA to reduce blood pressure. Accordingly, Applicants submit that a *prima facie* case of obviousness has not been established because of the failure of the combined references to teach each element of the Claims. Applicants request that the Claims be passed to allowance.

¹⁵ See MPEP §2144.03.

c. References do not Provide Reasonable Expectation of Success

The cited references do not provide a reasonable expectation of success for obtaining the claimed compositions. The Federal Circuit has held that "obvious to experiment" is not the standard for obviousness.¹⁶ The Dow court made it very clear that one must determine whether "the prior art would have suggested to one of ordinary skill in the art that this process **should** be carried out and **would** have a reasonable likelihood of success, viewed in light of the prior art." *Id.* at 1531 (Emphasis added).

As described above, the Langer reference states that there is a "relatively weak relation between weight loss and blood pressure . . ." Given this "relatively weak relation" Applicants fail to understand from the Examiner's reasoning how a person ordinarily skilled in the art would expect that CLA could be used to treat hypertension.

This argument is supported by the attached Declaration of Dr. Clement Ip. In the Declaration, Dr. Ip demonstrates that the effect of CLA is not due to weight loss as hypothesized by the Examiner, but instead is likely due to the action of CLA on genes known to be involved in hypertension, including those encoding angiotensin, angiotensin converting enzyme, angiotensin I receptor, angiotensin II receptor, endothelin converting enzyme, and ET-B endothelin receptor. Furthermore, Dr. Ip's interpretation of the Langer and Udell references is consistent with that advanced above, namely that a person of ordinary skill in the art would not believe upon reading the cited references reading the cited references that the body composition altering effects of CLA would have any relation to the treatment of hypertension. Accordingly, Applicants submit that even if the Examiner had established a prima facie case of obviousness, it has been rebutted. Accordingly, Applicants request allowance of the Claims.

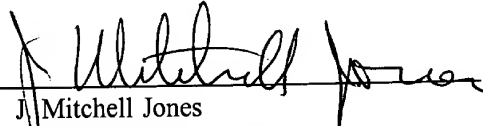
Conclusion

All grounds of rejection and objection of the Office Action of July 23, 2001 having been addressed, reconsideration of the application is respectfully requested. It is respectfully submitted that the invention as claimed fully meets all requirements and that the claims are worthy of allowance. Should the Examiner believe that a telephone interview would aid in

¹⁶ *In re Dow Chemical*, 5 USPQ2d 1529, at 1532 (Fed. Cir. 1988).

the prosecution of this application, Applicant encourages the Examiner to call the undersigned collect at (608) 218-6900.

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APPENDIX I
MARKED-UP VERSION OF REWRITTEN, ADDED,
AND/OR CANCELLED CLAIMS

The following is a version of the claims pursuant to 37 C.F.R. §1.121 (c)(1)(ii) with markings showing changes made herein to the previous version of record of the claims.

IN THE CLAIMS:

Please amend the Claims as follows:

9. (New) The method of Claim 1 wherein said safe and effective amount of conjugated linoleic acid is about 0.1 grams to 20 grams.